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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/26/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,788

Applicant(s)

Mahan et al

Examiner

Partner

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-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 9, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-9, 12, 13, 15, 18, 20, and 22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 12, 13, 15, 18, 20, and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11, 13 6) ☐ Other:

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DETAILED ACTION

Claims 13, 20 and 22 have been amended.

Claims 1-5, 7-9, 12-13, 15, 18, 20 and 22 are pending.

Claims 6,10-11,14,16-17, 19, 21 and 23-29 have been canceled.

Information Disclosure Statement

1. The information disclosure statements filed May 13, 2002 and July 8, 2002 have been considered.

Specification

2. The disclosure is objected to because of the following informalities:
 - a. At page 17, paragraph 0067 an image of a "hand" is recited. What is the hand intended to define?
 - b. At page 18, paragraph 0068 an image of a "hand" is recited. What is the hand intended to define?
 - c. At page 70, Table 1, just before paragraph 0248 an image of a "lined page" is recited. What is this image intended to define? Appropriate correction is requested.

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Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1,3-5, 7, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrases “live bacteria” and “unaltered pathogenic bacteria”. Are the live bacteria and the “unaltered pathogenic bacteria” variants of each other of the same genus and species? Does the unaltered pathogenic bacterial produce “Dam” naturally? The live bacteria is not defined to be pathogenic or non-pathogenic, nor is it defined to correspond to the pathogenic bacteria based upon genus or species; how are the two bacteria related to one another? What is the base line for “Dam” activity, if the pathogenic strain does not produce “Dam”? What produces the alteration in the activity?

Claim 3 recites the phrase “wherein the Dam activity is altered by a second heterologous nucleotide sequence”. While a dependent claim which recites a “wherein” clauses can clearly limit a claim from which they depend, a wherein clause that is set forth in the passive voice does not define a composition the --further comprises-- an additional nucleotide sequence. The composition of claim 1 from which claim 3 depends only comprises a first heterologous sequence and an alteration. The composition of claim 3 does not recite the phrase --further comprises--- “a

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second heterologous nucleotide sequence". The invention of claim 3 could be made clear by amendment of the claim to recite the phrase --further comprises--.

Claim 4 recite the phrase "wherein the first heterologous sequence is operatively inserted into a first expression cassette" and depends from claim 1 which sets forth the "first heterologous nucleotide sequence operatively inserted in the bacteria." Isn't the bacteria of claim 1 a type of expression system? How can both be true at the same time, if the first heterologous sequence has already been inserted into the bacteria in claim 1? How does claim 4 further limit claim 1 which already has a first heterologous sequence inserted? Does the bacteria of claim 4 comprise two copies of the first heterologous sequence? Is the "wherein" clause intended to further define the "inserted" sequence of claim 1?

Claim 5 depends from claim 3 and 1, and recites the phrase "operatively inserted into a second expression cassette". As no first expression cassette is defined in either of claims 1 or 3, and claims 1 and 3 do not recite the phrase "expression cassette", this phrase lacks antecedent basis in the claims from which claim 5 depends. Clarification is requested.

Claim 7 recites the phrase "wherein the genetically engineered change" and depends from claim 1. As claim 1 does not recite the phrase "genetically engineered change", thus the claim limitations of claim 7 lack antecedent basis in claim 1. Is alteration of claim 1 intended to be a genetically engineered change? If this is intended, it is not distinctly claimed.

Claim 18 recites the phrase "sexual transmitted disease". It appears that this phrase should recite --sexually-- to be clear.

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Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-5, 7-9, 12-13, 15, 18, 20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Curtiss, III et al (US Pat. 6,383,496).

The claimed invention is directed to an immunogenic composition of an attenuated live bacteria with an altered DNA adenine methylase (Dam) activity relative to wild-type activity of an unaltered pathogenic bacteria, and a first heterologous nucleotide sequence operative inserted in the bacteria, in such a way that the heterologous sequences expresses a heterologous antigen.

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(Instant claims 1-3) Curtiss, III et al disclose and claim an immunogenic composition of an attenuated live (see col. 18, line 41) bacteria with an altered DNA adenine methylase (Dam) activity (see col. 64, claims 25-26) relative to wild-type activity of an unaltered pathogenic bacteria, and a **first heterologous** nucleotide sequence (see col. 15, lines 42-55) operative inserted in the bacteria (see claim 27, col. 64, line 23), in such a way that the heterologous sequences expresses a heterologous antigen (see col. 16, line 2; claims 28-29) and a second heterologous sequence that alters the Dam activity due to the insertion of a second heterologous nucleotide sequence (see claims 23-30).

(Instant claims 4-5) The first and second heterologous nucleotide sequences are inserted into an expression cassette, wherein the expression cassette encodes first and second heterologous coding sequences (see Figures 6, 7 12, 13, 16).

(Instant claim 7) Among the mutations disclosed and used to attenuate the live bacteria, deletion mutations are taught to be non-reverting and non-lethal mutations to the bacteria (see claim 24, col. 64).

(Instant claims 8-9, 12 and 15) The heterologous antigen is disclosed to be an antigen of a virus or bacteria (see Curtiss, III, col. 64, claims 28-29) and is disclosed to include (Instant claim 12) pathogens that cause enteric infection (see Curtiss, III, col. 12, lines 53-67 and col. 13, lines 1-7) and pathogens that cause (Instant claim 15) respiratory infection (see col. 12, specifically line 47).

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(Instant claims 18) Among the specific microorganisms disclosed for which the heterologous nucleotide sequence will encode include *Bordetella pertussis* (see col. 12, line 51), *Chlamydia pneumoniae* (see Curtiss, III et al, col. 12, line 47), *Haemophilus influenzae* (see col. 12, lines 50-51), *Mycobacterium tuberculosis* (see Curtiss, III et al, col. 12, lines 51-52), *Mycoplasma pneumoniae* (see Curtiss, III et al col. 12, line 50), *Pseudomonas aeruginosa* (see Curtiss, III, col. 12, line 56), smallpox (poxviridae, col. 13, line 2), *Streptococcus* Group A or B (see Curtiss, III et al, col. 12, lines 47-49).

(Instant claim 13) Additional heterologous coded antigens are obtained from *Vibrio cholera* (see Curtiss, III et al, col. 12, line 53), (Instant claim 20) Retroviruses (HIV is a retro virus) (see Curtiss, III, col. 12, line 67) and (Instant claim 22) Hepatitis B (also known as Hepadnaviridae, see Curtiss, III et al, col. 13, line 1).

Inherently the reference discloses the instantly claimed invention.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Briggs et al (US Pat. 5,587,305) is cited to show dam- strain of bacteria (see col. 11, lines 7-35, especially line 12).

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9. Curtiss, III (US Pat. 5,672,345) is cited to show attenuated live bacterial vectors that express a heterologous antigen and comprise a dam-3 derivative strain (see col. 10, Table 1, strain number X2230).

10. Mitra et al (US Pat. 6,252,140) is cited to show mutated Chlorella virus DNA methyl transferase promoter nucleotide sequences, and expression cassettes inserted into prokaryotic cells for the expression of first and second DNA sequences (see Mitra et al, col. 30, claims 31-33 and claims 42-43).

11. Stein et al (US Pat. 5,491,060) is cited to show E.coli bacterial strains that evidence altered methyl transferase activity.

12. Stewart, Jr. et al (US Pat. 6,261,561) is cited to show a live attenuated bacterium with a dam mutation (see col. 13, lines 6-19).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

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The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

August 19, 2002

Nita Minnifield
NITA MINNIFIELD
PRIMARY EXAMINER
8/20/02